OCT 2 0 2004

K042002
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510 (k) Summary of Safety and Effectiveness

Submitter:

ELA Medical, Inc.
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Contact Person:

Susan Olive, Regulatory Affairs Manager

Devices trade names / Common names:

- Trade Name: SyneScope™
  - Common name: Holter ECG analysis software (or Holter ECG analyzer, or Holter ECG scanner).
- Trade Name: EasyScope™
  - Common name: Holter ECG analysis software (or Holter ECG analyzer, or Holter ECG scanner).
- Trade Name: SyneCom™
  - Common name: Holter ECG data transfer software or system.
- Trade Name: HolterReader
  - Common name: Holter ECG report viewer and printing software or tool.

Note: SyneCom™ and HolterReader are considered accessories of Holter ECG analyzers (they can be distributed separately to analyzers but they are intended to be used in conjunction with them).

Classification name:

Computer, diagnostic, programmable
DQK (21CFR 870.1425)

Predicate devices:

The legally marketed devices to which ELA Medical is claiming equivalence are:

- **SyneTec (ELA Medical):** ELA Medical "SyneTec™" (510(k) K002817, ELA Medical Inc.).
- **SyneView (ELA Medical):** ELA Medical "SyneView™" (510(k) K990727, ELA Medical Inc.) including SyneView2™.
- **H-Scribe (Mortara):** Mortara Instrument, Inc. "H-Scribe" (510(k) K004017, Mortara Instrument, Inc.).

- **Holter For Windows + (Rozinn):** Rozinn Electronics, Inc. "Holter For Windows +" (based on 510(k) K930564, Northeast Monitoring, Inc.) including also Rozinn Electronics, Inc. "Netlink/NetScan" (510(k) K020213, Rozinn Electronics, Inc.).
- **Mida (Ortivus sold by Philips Medical Systems)**: based on "Mida System Models 1000/1100" (510(k) K896396, Medical Graphics Corp.)

Device description:

SyneScope™, EasyScope™, SyneCom™ and HolterReader are software applications that allow evaluation of Holter recordings obtained with an ELA Medical Holter ECG digital recorder [SyneFlash™(K990727) and SpiderView™ (K032466)], a standard cassette tape recorder, or an ISHNE compatible recording (for SyneScope™ only).

SyneScope™, EasyScope™, SyneCom™ and HolterReader are Microsoft Windows-based applications that run on personal computers equipped with flash-card readers and/or tape cassette readers.

Intended use:

SyneScope™ is intended to analyze, edit, review, report, store and transfer multi-channel ECG recording on pediatric or adult patients (for periods up to 96 hours). These recordings are provided by:

- SpiderView™ Holter ECG recorder (K032466),
- SyneFlash™ Holter ECG (K990727), or
- other compatible cassette tape recorder.

In addition, any ISHNE compatible recording can be read by SyneScope™.

EasyScope™ is intended to analyze, edit, review, report, store and transfer 2-3 channel ECG recording on pediatric or adult patients (for periods up to 96 hours). These recordings are provided by:

- SpiderView™ Holter ECG recorder (K032466),
- SyneFlash™ Holter ECG (K990727), or
- other compatible cassette tape recorder.

SyneCom™ is intended to download, transfer for analysis, print and store multi-channel ECG recordings on pediatric or adult patients (for periods up to 96 hours). These recordings are provided by:

- SpiderView™ Holter ECG recorder (K032466) or
- SyneFlash™ Holter ECG (K990727).

HolterReader is intended to view and print Holter report from SyneScope™, EasyScope™ and SyneCom™.

SyneScope™, EasyScope™, SyneCom™ and HolterReader are intended to be used under the supervision of licensed and trained practitioners, in a hospital or clinic setting. Applications for Holter monitoring include, but are not limited to, evaluation of the following:

- Patient symptoms such as syncope, dizziness or palpitations.
- Ischemia, especially in patients who cannot exercise or in patients with variant angina.
- Function of an implanted pacemaker or defibrillator.

Comparison of technology characteristics to predicate devices:

Model	SyneScope	EasyScope	SyneTec	SyneView / SyneView 2	H-Scribe	Holter for Windows
Company	ELA Medical	ELA Medical	ELA Medical	ELA Medical	Mortara	Rozinn
510(k) Number			K002817	K990727	K004017	K930564
CE / MDD certification	Yes	Yes	Yes	Yes	Yes	Yes
Type	Holter Analyzer	Holter Analyzer	Holter Analyzer	Holter Analyzer	Holter Analyzer	Holter Analyzer
PC based	Yes	Yes	Yes	Yes	Yes	Yes
Operating System	Microsoft Windows	Microsoft Windows	Microsoft Windows	Microsoft Windows	Microsoft Windows	Microsoft Windows
Network Compatible	Yes	Yes	Yes	Yes	Yes	Yes
Read digital	Yes	Yes	Yes	Yes	Yes	Yes
Cassette Tape	Yes	Yes	Yes	Yes	Yes	Yes
ECG Channels	Basic: 2/3 Max: 12	Basic: 2/3 Max: 3	Basic: 2/3 Max: 3	Basic: 2/3 Max: 3	Basic: 2/3 Max: 12	Basic: 2/3 Max: 12
Multi-Channel Arrhythmia Analysis	Yes	Yes	Yes	Yes	Yes	Yes
24H Full Disclosure	Yes	Yes	Yes	Yes	Yes	Yes
ST deviation analysis	Yes	Yes	Yes	Yes	Yes	Yes
Pacemaker Activity	Yes	Yes	Yes	Yes	Yes	Yes
Trend Review	Yes	Yes	Yes	Yes	Yes	Yes
Templates editing	Yes	Yes	Yes	Yes	Yes	Yes
Beat to Beat editing	Yes	Yes	Yes	Yes	Yes	Yes
Strip editing	Yes	Yes	Yes	Yes	Yes	Yes
ECG Superimposition	Yes	Yes	Yes	Yes	Yes	Yes
Page Mode	Yes	Yes	Yes	Yes	Yes	Yes
Editing report	Yes	Yes	Yes	Yes	Yes	Yes

Model	SyneScope	EasyScope	SyneTec	SyneView / SyneView 2	H-Scribe	Holter for Windows+
Company	ELA Medical	ELA Medical	ELA Medical	ELA Medical	Mortara	Rozinn
510(k) Number			K002817	K990727	K004017	K930564
Customized report	Yes	Yes	Yes	Yes	Yes	Yes
Archiving	Yes	Yes	Yes	Yes	Yes	Yes
Printing ECG strip	Yes	Yes	Yes	Yes	Yes	Yes
Printing Full Disclosure	Yes	Yes	Yes	Yes	Yes	Yes
Import/Export capabilities	Yes	No	Yes	No	Yes	Yes
Import ASCII RR Files	Yes	No	Yes	No		
Export Results in ASCII format	Yes	No	Yes	No		
Export RR or HR files in ASCII format	Yes	No	Yes	No		
Export ECG files in ISHNE format	Yes	No	Yes	No		
Read High Resolution ECG file	Yes	No	Yes	No		
Export High Resolution ECG files in ISHNE format	Yes	No	Yes	No		
Heart Rate Variability (HRV)	Yes	Partial	Yes	Partial	Yes	Yes
Time Domain (TD)	Yes	No	Yes	No	Yes	Yes
Frequency Domain (FD)	Yes	No	Yes	No	No	Yes
Multiday	Yes (96H)	Yes (96H)	No	No	Yes (48H)	Yes (48H)
True 12-Lead ECG	Yes	No	No	No	Yes	Yes
12-Lead ECG Derived	Yes (Dower method - from XYZ-Lead system)*	No	No	No	No	No
12-Lead ST segment analysis	Yes	No	No	No	Yes	Yes
Holter Data Transfer	Yes (like SYNECOM)	Yes (like SYNECOM)	No	No	Yes	Yes
Holter ECG Report Viewer/Editor	Yes (Holter Reader)	Yes (Holter Reader)	No	No	Yes	Yes
Import ISHNE ECG file	Yes	No	No	No	No	No
Internet	Yes	Yes	No	No	Yes	Yes (with Netlink/Netscan, K020213)

* see Attachment 10.8 for details.

Summary of Studies:

The following functional testing was performed on the SyneScope™, EasyScope™, SyneCom™ and HolterReader:

Test group	Tests	Report of results
SyneScope™, EasyScope™, SyneCom™ and HolterReader safety and performance testing.	Safety and performance tests according to the AAMI/ANSI EC38:1998 & IEC 60601-2-47 standards.	See Attachment 10.9.
SyneScope™, EasyScope™, SyneCom™ and HolterReader software verification and validation testing.	Module and functional testing for SyneScope™, EasyScope™, SyneCom™ and HolterReader software applications	See Attachment 10.6.
SyneScope™, EasyScope™, SyneCom™ and HolterReader field testing	Field validation protocol and evaluation form completion.	See Attachment 10.4.

All test systems were representative of final production devices unless otherwise specified.

Compliance with European Medical Device Directive 93/42/CEE and European standards IEC-60601-2-47 was verified.

See Attachment 10.7 for copies of the SyneScope™, EasyScope™, SyneCom™ and HolterReader declarations of conformity and CE certificates.

Conclusion:

The information presented in this submission provides reasonable assurance that the SyneScope™, EasyScope™, SyneCom™ and HolterReader will perform in a safe and effective manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2004

ELA Medical, Inc.
c/o Ms. Susan Olive
Regulatory Affairs Manager
2950 Xenium Lane North, Suite 120
Plymouth, MN 55441

Re: K042002
Trade Name: SyneScope™, EasyScope™, SyneCom™, and HolterReader Holter Analyzers
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: July 23, 2004
Received: July 26, 2004

Dear Ms. Olive:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K042002

Device Name:

SyneScope™ (Holter ECG analysis software or Holter ECG analyzer, or Holter ECG scanner).

EasyScope™ (Holter ECG analysis software or Holter ECG analyzer, or Holter ECG scanner)

SyneCom™ (Holter ECG data transfer software or system)

HolterReader (Holter ECG report viewer and printing software or tool)

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- SpiderView™ Holter ECG recorder (K032466),
- SyneFlash™ Holter ECG (K990727), or
- other compatible cassette tape recorder.

SyneCom™ is intended to download, transfer for analysis, print and store multi-channel ECG recording on pediatric or adult patients (for periods up to 96 hours). These recordings are provided by:

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- SyneFlash™ Holter ECG (K990727)

HolterReader is intended to view and print Holter reports from SyneScope™, EasyScope™ and SyneCom™.

SyneScope™, EasyScope™, SyneCom™ and HolterReader are intended to be used under the supervision of licensed and trained practitioners, in a hospital or clinic setting. Applications for Holter monitoring include, but are not limited to, evaluation of the following:

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- Ischemia, especially in patients who cannot exercise or in patients with variant angina.
- Function of an implanted pacemaker or defibrillator.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number k042002